K123141

510(k) Summary

OCT 25 2012

Company
Ethicon Endo-Surgery, LLC
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Guaynabo, PR 00969

Contact
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Date Prepared: October 4, 2012

Device Name
Trade Name: ENSEAL Trio Tissue Sealing Device
Common Name: Electrosurgical Cutting and Coagulation Instruments

Classification Names

- Electrosurgical, Cutting & Coagulation & Accessories
  (21 CFR 878.4400, Product code GEI)
- Electrocautery, Gynecologic and Accessories
  (21 CFR 884.4120, Product code HGI)

Predicate Device
ENSEAL Trio Tissue Sealing Device, Cleared as: The EnSeal™ PTC Tissue Sealing Device of the EnSeal™ Vessel Sealing and Hemostasis system, K070896

Device Description:

The Ethicon Endo-Surgery ENSEAL Trio Tissue Sealing Devices are sterile, single-use surgical instruments designed to seal and cut vessels, and to cut, grasp and dissect soft tissue during open and laparoscopic surgery.

The instrument shaft can be rotated using the rotation knob to facilitate visualization and enable easy access to targeted tissue. The power cord is permanently attached to the device and connects the instrument to the generator.

Intended Use:

The ENSEAL Trio Tissue Sealing Device is a bipolar electrosurgical instrument for use with a radiofrequency generator. It is intended for use during open or laparoscopic, general and gynecologic surgery to cut and seal vessels, cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection

is performed. The devices can be used on vessels up to (and including) 7 mm and bundles as large as will fit in the jaws of the instruments.

The Ethicon Endo-Surgery ENSEAL Trio Tissue Sealing Device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

Technological Characteristics:

The Ethicon Endo-Surgery ENSEAL Trio Tissue Sealing Devices have a 5 mm diameter shaft and are available in 4 shaft lengths: 14cm, 25cm, 35cm and 45cm; and a 3mm curved jaw. The jaws are provided in the opened position and can be partially or fully closed by squeezing the closing handle. The device jaws can grasp and hold targeted tissue when clamped. The device uses a combination of bipolar electrosurgical energy in conjunction with the I-BLADE knife, to compress, coagulate, and transect tissue.

In addition to the similar technological characteristics as the Predicate, the ENSEAL Trio Tissue Sealing Devices have a modification to the device jaws. The modified jaws are manufactured using a brazed assembly process; the predicate jaws are manufactured using an epoxy assembly process. The Subject device jaws seal and cut vessels, and cut, grasp and dissect soft tissue as intended.

The modification described in this submission does not affect the intended use of the device or alter the fundamental scientific technology of the device, and summary information that results from the design control process serve as the basis for this submission along with the required elements of a 510(k) found in 21 CFR 807.87.

Performance Data:

Ex-vivo tests (bench) were performed to ensure that the devices perform as intended and meet design specifications. Device performance was assessed against the design requirements, and included Electromagnetic Compatibility, Electrical Safety, Force to Fire, Force to Cut, Air Leak Rate, Device Durability. Vessel Burst Pressure, Jaw Strength, and Activation Performance.

Testing for all materials is in accordance with the standards AAMI/ANSI/ISO 10993-1:2009 and on FDA General Program Memorandum #G95-1: Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing."

Conclusion:

The Ethicon Endo-Surgery ENSEAL Trio Tissue Sealing Devices are substantially equivalent to the legally marketed Predicate device based upon intended use, technological characteristics, and performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Incorporated
Ms. Emily Kreutzkamp
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

OCT 25 2012

Re: K123141
Trade/Device Name: ENSEAL® Trio Tissue Sealing Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HGI
Dated: October 04, 2012
Received: October 05, 2012

Dear Ms. Kreutzkamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K123141

Device Name: ENSEAL® Trio Tissue Sealing Device

INDICATION FOR USE

The ENSEAL Trio Tissue Sealing Device is a bipolar electrosurgical instrument for use with a radiofrequency generator. It is intended for use during open or laparoscopic, general and gynecologic surgery to cut and seal vessels, cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7 mm and bundles as large as will fit in the jaws of the instruments.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical Orthopedic,
and Restorative Devices

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